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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/795,946	03/08/2004	Denis Pichon	OSTEONICS 3.0-454	1423
530 7590 02/22/2007 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			EXAMINER PELLEGRINO, BRIAN E	
			ART UNIT 3738	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/22/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/795,946

Applicant(s)

PICHON ET AL.

Examiner

Brian E. Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11-19 and 24-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11-19 and 24-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 3/8/04, 7/19/04.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of Specie I (Figs. 1,2) in the reply filed on 12/4/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election *without* traverse (MPEP § 818.03(a)).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8,11-19,24-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claims 1 and 24, the phrase "and/or" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "and/or"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d). It is not clear if the prosthesis has both portions or just one. Or is the Applicant using alternative terms for one part?

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8,17,28,29 are rejected under 35 U.S.C. 102(b) as being anticipated by Park (6217620). Park discloses (Fig. 4) a femoral prosthesis comprising a shoulder and/or neck portion with a stem **220** for insertion into a femoral canal. Fig. 5 shows a sleeve to circumferentially surround the stem. The sleeve has multiple sleeve components **302**, **304** that form medial and lateral sides. The columns **304** are joined together via the coils **302**. It can also be seen (Fig. 5) that the sleeve provides a central bore and that it is tapered to accommodate the tapered stem shown in Fig. 4. Also shown within the sleeve are pegs or means **306** to secure the sleeve on a position of the stem. Fig. 7 shows the sleeve positioned on the proximal portion of the stem and is placed there for support, col. 9, lines 32-35.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11,13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park '620 in view of McCarthy (5549706). Park is explained supra. However, Park fails to disclose means to attach a separate shoulder and/or neck portion to the stem. McCarthy teaches (Figs. 1-10) that the prosthesis can be made to have separate

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attaching shoulder and neck portions provided with means to attach these components. Figs. 7,8 show the neck is held in position on a tapered portion of the stem by a screw. McCarthy also teaches that the prosthesis is provided with modular components such that the proper geometry can be obtained to match the contour of the intramedullary canal for the patient, col. 1, lines 62-67. It would have been obvious to one of ordinary skill in the art to utilize modular shoulder and neck portions as taught by McCarthy with the prosthesis of Park such that the proper match can be formed for the patient as the surgeon implants the device.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Park '620 in view of Fallin (5108452). Park is explained supra. However, Park fails to disclose means to attach a ball head. Fallin teaches (Fig. 5) a separate ball head **27** and means **45** to attach to the neck **14** of the stem **17**. Fallin teaches that extension members **45** permit different sizes to be used to accommodate the patient's requirements, col. 7, lines 67,68, col. 8, lines 1-3. It would have been obvious to one of ordinary skill in the art to utilize means to attach a separate head as taught by Fallin with the prosthesis of Park such that the surgeon can anatomically match the implant with the patient's repair site.

Claims 1,12,18,19,28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noiles (4846839) in view of Ferree (2004/24469). Noiles discloses (Fig. 1) a femoral prosthesis having a stem **12**, a neck **14**, and a proximal sleeve **18**. Figs. 2 and 3 show the sleeve has an interior shape that is symmetrical and an exterior that is non-symmetrical or partly circumferential. However, Noiles fails to disclose the

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sleeve formed as two components. Ferree teaches (Figs. 8A,8B) that sleeves for femoral prostheses can be formed as two parts with screws to tighten the two pieces together. Ferree also teaches that this structure permits the sleeve to be tightened and adjusted to a degree for decreasing motion between the prosthesis and bone, paragraphs 73,74. It would have been obvious to one of ordinary skill in the art to utilize adjustable means and two sleeve components as taught by Ferree with the prosthesis of Noiles such that the surgeon can adjust the implant within the patient's intramedullary canal to a set position and prevent movement.

Claims 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noiles '839 in view of Ferree (2004/24469) and Fallin '452. Noiles in view of Ferree is explained supra. As mentioned above Noiles fails to disclose two sleeve portions and a plurality of prosthetic femoral components. Fallin teaches a plurality of prosthetic femoral components, Figs. 1,3,4. Fallin also teaches that it is advantageous to provide a kit or plurality of components for the surgeon to use to enable the surgeon to properly fit a prosthesis in the patient according to the anatomical dimensions encountered, col. 3, lines 31-37. Fallin additionally teaches separate neck portions attachable to the stem. It would have been obvious to one of ordinary skill in the art to provide a kit of components and utilize adjustable means and two sleeve components as taught by Fallin and Ferree respectively with the prosthesis of Noiles such that the surgeon can properly adjust the implant within the patient's intramedullary canal to a set position and prevent movement.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-F (9am-5:30pm) .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700, AU 3738



**BRIAN E. PELLEGRINO**  
**PRIMARY EXAMINER**